T-Stat® 303 Prescribing Information

Rx Only

***General Description*:**

T-Stat® 303 Ischemia Detection System is a broadband, multi-wavelength, Visible Light Spectroscopy (VLS) ischemia detection system, sensitive in real time to the presence of local ischemia.

A complete T-Stat® 303 system consists of a single-use disposable catheter connected to a monitor. Illumination of the tissue is provided by a light source within the catheter. Reflected light from mucosal tissue is captured and returned to the monitor. Tissue ischemia is detected by estimating the microvascular hemoglobin oxygen saturation using differential optical diffuse reflectance spectroscopy and fitting for background scattering over a range of reflected visible wavelengths.

Single-use catheters are available for oral, catheter, nasal/endoscopic, hand-held spot-check use.

***Clinical Studies*:**
In peer-reviewed studies of T-Stat® submitted to the FDA for pre-approval review:

- T-Stat® was sensitive to reduced-flow and no-flow ischemic states ($p<0.001$) [1,2].
- T-Stat® provided readings in low-flow and no-flow ischemic states [1,2].
- T-Stat® VLS measures (Sto_2) are unbiased in comparison to NIRS measures (Sto_2% Bias = –1%±5%, p=N.S.)
- T-Stat® VLS demonstrated significantly tighter ranges of normal than NIRS (VLS ±3% vs. NIRS ±9%, $p<0.001$) [1].

***Indications for Use*:**

The Spectros T-Stat® 303 Microvascular Tissue Oximeter is intended for use as an adjunct monitor of the localized hemoglobin oxygen saturation of blood in the microvascular tissue spaces (Sto_2) in infants, children, or adults at risk for reduced-flow and no-flow ischemic states.

The prospective clinical value of measurements made with the T-Stat® Oximeter has not been demonstrated in disease states. The T-Stat® Oximeter should not be used as the sole basis for diagnosis or therapy.

***Precautions*:**

- T-Stat® measures locally, and may not reflect changes in oxygenation that occur in regions outside of that monitored by the T-Stat® catheter.
- T-Stat® used alone at a single site cannot differentiate between local and global ischemic conditions.
- Use of T-Stat® during high-output shock states such as sepsis has not been evaluated. During these conditions, central venous saturation may be normal or elevated, and the ability of T-Stat® to detect tissue hypoxia is unknown.
- Normal T-Stat® values in liver and the small intestine have not yet been established, as these readings are affected by organ pigments and surface bile (respectively).
- Catheters are supplied sterile for single use. Do not reuse.

References:
[1] Anesthesiology. 2004 Jun;100(6):1469-75.
[2] Gastrointest Endosc Clin N Am. 2004 Jul;14(3):539-53, ix-x.
[3] J Biomed Optics 2005; Jul/Aug 10(4).
[4] Pediatric Crit Care Med 2005;6(6):671-675.
[5] J Surgical Research 2006; in press.
[6] Data on file.
[7] Continuous monitoring reduced blood sampling in indwelling Svo_2 studies.